BARNES & THORNBURG LLP

P.O. Box 2786
Chicago, Illinois 60690
(312) 357-1313
(312) 759-5646 Fax

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit:	1615
Confirmation No.:	7930
Application No.:	10/686,797
Invention:	METHOD FOR PROVIDING LONG-LASTING PAIN DIMINISHMENT THROUGH TOPICAL OR INTRANASAL ADMINISTRATION OF CIVAMIDE
Inventor:	BERNSTEIN, Joel E.
Filed:	October 16, 2003
Attorney Docket:	41957-102740
Examiner:	Carlos A. Azpuru

Certificate Under 37 CFR 1.8(a)

I hereby certify that this correspondence is being electronically filed via EFS WEB addressed to: Mail Stop Amendment Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

on June 30, 2006

Alice O. Martin
(Signature)

Alice O. Martin
(Printed Name)

DECLARATION UNDER 37 CFR §1.132 OF JOEL E. BERNSTEIN, M.D.

1. I, Joel E. Bernstein, M.D., am the inventor and applicant of U.S. Patent Application No. 10/686,797 entitled, "Method For Providing Long-Lasting Pain Diminishment Through Topical or Intranasal Administration of Civamide."

2. I am a citizen of the U.S.A. and the state of Illinois and I reside at 615 Brierhill Road, Deerfield, Illinois 60015.

3. I have read the Office Action of April 24, 2006 and participated by telephone in the interview conducted by Dr. Alice Martin at the U.S. Patent Office in Washington, D.C. with Examiner Azpuru on May 21, 2006.

4. I understand that the examiner's opinion is that a showing of "unusual or unexpected results" is required to overcome the only remaining rejection, obviousness.

Although I disagree this is necessary, I submit the following evidence of unusual and unexpected results.

5. I declare that the enclosed exhibits (B and C) including reports of clinical trials of the invention that is the subject of the patent application captioned above, provide evidence of "unusual and unexpected results."

6. Exhibit A is U.S. Patent No. 5,063,060 on which the examiner bases his obviousness rejection. I am also the applicant and inventor of this patent entitled "Compositions And Method For Treating Painful, Inflammatory or Allergic Disorders".

7. Patent No. 5,063,060 teaches that civamide (cis-8-methyl-N-vanillyl-6-nonenamide) is a stereoisomer of the widely used chemical capsaicin. Exhibit A further teaches that civamide and capsaicin are utilized in identical fashion and are comparable in efficacy with the only significant difference being that civamide has less local adverse effects than those normally associated with capsaicin.

8. Exhibit A further teaches that civamide is administered identically to capsaicin, which means multiple administrations every day on a continuous basis in order to provide effective analgesia. A corollary of this teaching is that when either drug is discontinued the analgesic effects, as with virtually all other drugs, immediately cease.

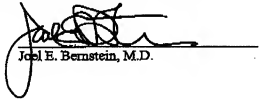
9. Exhibits B and C are summaries of clinical studies which substantiate the novel and unanticipated method of treatment with topical and intranasal civamide described in U.S. Patent Application No. 10/686,797. These summaries demonstrate the unusual and unexpected effects of treatment with civamide nasal spray and civamide cream where patients had continuing relief of headache or arthritis pain for several months after short-term administration of the civamide formulations. That is, analgesic effects did not cease after administration of civamide ceased.

10. In a Phase II study (Exhibit B) 1103-5651-01, investigators reported that many patients exhibited relief of their osteoarthritis pain for periods as long as 2-4 months after completing the course of treatment with civamide.

11. In another Phase II study (Exhibit B) (1103-5651-03), similarly to the 1103-5651-01 study, many patients reported continued relief from osteoarthritis pain for as long as 4 months following discontinuance of civamide.

12. In 2 Phase III studies of the civamide nasal (0.01%) solution (Exhibit C) (WL-1001-0202 and WL-1001-0283), the study was conducted in sequential phases - after a Screening Period and Baseline Period, there was a 7-day Treatment Period, followed by a 42-day Post Treatment Observation Period. Unusual and unexpected results again showed relief post treatment, for example, the frequency of cluster headaches declined continuously over the 42-day Post-Treatment period for patients treated with civamide, with a 65% reduction in headaches by week 6. (See also WL-1001-02-01)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon



Joel E. Bernstein, M.D.

CHDS01 AOM 337913v1